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EXAMINER

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| ART UNIT | PAPER NUMBER |
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DATE MAILED: 07/02/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**



☒ Claim(s) 1-30 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-30 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**

## DETAILED ACTION

**Preliminary amendment dated 2-7-01 is acknowledged.**

**Claims included in the prosecution are 11-30.**

*Claim Rejections - 35 U.S.C. § 112*

1. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

2. **Claims 16, 18, 21, 23, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**It is unclear what applicant intends to convey by 'a natural product or extract containing hydroxy citric acid or salt or ester thereof in claim 16.**

**'the fruit' in claim 18 lacks an antecedent basis in claim 16.**

**What is 'vegetal fiber' as recited in claim 21?**

**What is a 'semisolid' or 'semiliquid' as recited in claim 23?**

**What is being conveyed by 'in a vial suitable for oral or rectal or topical administration" as recited in claim 24?**

**It is unclear what applicants' intend to convey by 'facilitating the metabolism of lipids' in claim 26. Is it in normal humans? Also, metabolism includes both catabolism and anabolism. Which one is being referred to? In what tissue?**

*Double Patenting*

3. **The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

**A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).**

**Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).**

4. **Claim 30 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,217,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic claim encompasses the species of the components and their ratios claimed in the claims of said patent.**

*Claim Rejections - 35 U.S.C. § 102*

5. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

6. **Claims 11-15, 19-21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiegand (3,810,994) or Burtle (5,030,657).**

**Weigand teaches compositions containing carnitine or esters of carnitine and pantothenic acid for the treatment of obesity, reduced caloric intake and facilitate the fatty acid metabolism (note the abstract, columns 2-3 and claims).**

**Burtle teaches compositions containing carnitine or esters of carnitine and pantothenic acid (note the abstract, column 7 and claims).**

*Claim Rejections - 35 U.S.C. § 103*

7. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention**

was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigand cited above by itself or further in view of Moffett (5,536,516).

Weigand teaches that the anti-obesity compound can be administered along with other anti-obesity compounds (column 3). Weigand however, does not specifically teach that compound to be hydroxy citrate or that hydroxycitrate be in the form of Garcinia extract. The use of an art known anti-obese agent such as hydroxycitrate in combination with carnitine would have been obvious to one of ordinary skill in the art since Weigand advocates such a use. An artisan would be further motivated to use hydroxycitrate or hydroxycitrate containing Garcinia extract since Moffet teaches that this compound is known to reduce the body weight and therefore prepares a concentrate rich in this compound from Garcinia (note the abstract, col. 1, line 5 et seq.)

9. Claims 11-15, 19-20 and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigand cited above further in view of Leung (5,039,698).

As pointed out above, Weigand teaches that the anti-obesity compound can be administered along with other anti-obesity compounds (column 3). It is unclear from Weigand whether he considers pantothenic acid also taught to be anti-obese compound. The use of an art known anti-obese agent such as a pantothenate in combination with carnitine would have been obvious to one of ordinary skill in the art since Weigand

**advocates such a use. An artisan would be further motivated to use pantothenate since Leung teaches that this compound is a known weight reducing agent (note the abstract and claims).**

**10. Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination.**

**Hastings teaches dry formulations containing calcium salt of hydroxy citric acid, L-carnitine salt, Chromium, antioxidants and other components for weight loss (note the abstract, columns 1-5, examples and claims). Although Hastings does not specifically teach that the composition is in the form of semi-solid, semi-liquids, such is inherent since Hastings teaches the mixing of the composition with a liquid and depending upon the dissolvability of the composition, one would end up with a semi-solid composition. As pointed out above, Hastings teaches the oral administration of a composition containing carnitine and hydroxy citric acid. Hastings' does not however, teach various forms of the composition, such as a tablet or capsule or other claimed forms. It is deemed obvious to an artisan to select a proper form of the composition from Hastings' oral administration of the same composition, to obtain the best possible results. Hastings does not teach alkanoyl-carnitine. It would however be obvious to an artisan to use various forms of carnitine from Hastings' teachings with the expectation of obtaining at least similar results since the active agent is carnitine.**

**Weigand teaches compositions containing carnitine or esters of carnitine and pantothenic acid for the treatment of obesity. The composition can be administered orally or parenterally (note the abstract, columns 2-3 and claims).**

**Burtle teaches compositions containing carnitine or esters of carnitine and pantothenic acid (note the abstract, column 7 and claims).**

**The use of various forms of carnitine such as esters instead of carnitine itself as taught by Hastings would have been obvious to one of ordinary skill in the art since the references of Burtle and Wiegand show that the esters of carnitine are known to be used for the treatment of obesity; one would expect at least similar results.**

**11. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, further in view of applicant's statements of prior art.**

**Hastings, Wiegland and Burtle do not teach the addition of hydroxy citric acid in the form of a natural plant extract containing said acid. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to add the claimed extracts which according to applicant are well known extracts containing the hydroxy citric acid (page 4 of the specification), with the expectation of obtaining at least similar effect as that observed with the hydroxy citric acid itself.**

**12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings cited above by itself, or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, further in view of Weiner (1989) by itself or in combination with Stracher (5,008,288).**

**The references of Hastings, Wiegand, Burtle do not teach the administration of the composition in liposomes as vehicles.**

**The use of liposomes as carriers for the composition containing carnitine would have been obvious to an artisan since Weiner teaches the advantages of liposomes as drug delivery devices (note page 1523 and 1553) and also in view of the art known use of liposomally encapsulated carnitine derivatives as evident from Stracher (note the abstract). Applicant has not shown any unexpected results.**

**13. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand or Burtle; or Wiegand in view of Moffett: or Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination as set forth above, further in view of Cavazza (4,268,524).**

**Weigand, Burtle, Moffett and Hastings do not explicitly teach that the carnitine derivatives lower cholesterol and triglyceride levels.**

**Cavazza teaches that acetylcarnitine lowers both cholesterol and triglyceride levels (note the entire patent). It would have been obvious to one of ordinary skill in the art that the compositions taught by Wiegand, Burtle, Moffett and Hastings would lower cholesterol**

**and triglycerides and therefore could be used for hypertriglyceridaemia and hypercholestolaemia.**

**The references cited were cited in applicant's prior patent.**

**14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility**

**that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**

**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

***gsk***

**June 28, 2001**